REMARKS

Entry of the foregoing and favorable consideration of the subject application, in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the foregoing amendment, claims 49, 50, 51, 57, 58 and 61 have been amended. In particular, claims 49, 50, 51, 57, 58 and 61 have been amended to be in independent form by incorporating the subject matter of claim 35 therein. Claims 49, 50, 57 and 58 have been further amended to recite "a promoter." No new matter has been added.

Initially, the Examiner has acknowledged applicant's election of Group II, claims 49-52, 62-65, 76-79 and 83-86, with traverse. However, after applicants have made their election on the basis of the claims the Examiner originally indicated as being grouped together as Group II, the Examiner has now indicated that only claims 57, 58, 60 and 108-119 will be examined with Group II. The Examiner has stated that claims 64, 65, 78, 79, 85 and 86 were improperly included in Group II and should have been part of Group III. Applicants believe it is fundamentally unfair to revise the grouping of claims after the fact without permitting applicants the opportunity to shift their election. The undersigned representative contacted Examiner McGarry to discuss this situation and Examiner McGarry indicated that a petition under 37 C.F.R. § 1.144 would need to be filed. Thus, applicants intend to file such a petition.

Claims 49-52, 57-58, 60-63, 76-77, 83-84, and 108-119 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to

particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, claims 49, 50, 51, 57, 58 and 61 have been amended so as to be in independent form by adding the subject matter of withdrawn claim 35. These claim amendments do not narrow the scope of the amended claims or any element recited therein. Claims 49 and 50 have also been amended to recite "a promoter."

In light of the above, withdrawal of the rejection under 35 U.S.C. § 112, second paragraph is respectfully requested.

Claims 49-52, 57-58, 60-63, 76-77, 83-84, and 108-119 have also been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was purportedly not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claims invention at the time the application was filed. This rejection is respectfully traversed.

The Examiner has acknowledged that applicants provide sufficient written description support for SEQ ID NO:1. However, the Examiner argues that the subject application lacks adequate written description for "sequences that have a recited degree of identity (similarity, homology)" with SEQ ID NO: 1 and sequences "that hybridize to SEQ ID NO: 1." Office Action at 5-6.

Applicants respectfully disagree with the Examiner's assertion regarding the sequences with a certain homology and sequences which hybridize to SEQ ID NO: 1. The specification specifically recites a hybridization stringency (see, for example,

page 5, lines 7-13) as well a particular numerical figures with respect to the percent of nucleotide identity (see, for example, page 5, line 39 through page 6, line 2) together with a functional enzyme activity description (α1,3-fucosyl transferase). As such sufficient written description support exists for the claimed invention.

Homology of 50% to sequence SEQ ID NO: 1 is not to a too high number of possible DNA molecules so that the person skilled in the art would not be able to detect and isolate the inventive DNA molecules without undue burden.

With the help of programs, such as BLAST at the EMBL or SWISSPROT internet sites, it is possible to define the exact percentage of homology or identity between two given sequences. This is a very common method and since it is carried out electronically the result can be expected immediately. Furthermore, since these programs are accessible on internet this method can be carried out from any computer or processor without the need of additional equipment.

Various methods are known of how to find sequences which could show at least 50% homology to SEQ ID NO: 1 and which therefore potentially fall within the scope of protection of the claims of the present application. One possibility is defined in the present application whereby a known DNA molecule, for example the inventive DNA molecule of the present application, which codes for a GlcNAc-α1,3-fucosyl transferase is added to a sample and sequences which bind to this added DNA molecule can be tested for homology as mentioned above. Another possibility would be to check data bases for published sequences which potentially fall within the scope of the claimed invention of the present application and to check these with respect to homology according to the method as mentioned above.

These are only examples of how potential DNA molecules can be provided with which the homology test as mentioned above can be carried out. These methods (among others) belong to basic techniques which can be carried out by any person with basic laboratory experience in this technical field. Therefore, the person skilled in the art will be able to isolate or detect a DNA molecule (on the basis of the knowledge of SEQ ID NO: 1) and to verify the percentage of homology between the detected DNA molecule and the sequence according to SEQ ID NO: 1 without undue burden.

A further feature of the claimed DNA molecule of the present application is that the DNA molecule must code for a protein with fucosyl transferase activity. In order to test this, the basic method comprises adding the respective protein to a sample comprising labeled fucose and an acceptor which may be any peptide to be glycosylated. This acceptor may be, for example, bound to a carrier which will facilitate the detection. After a reaction time, the sample is usually washed and a content of bound fucose to the acceptor is measured. The activity of the fucosyl transferase is defined in the present application as being positive if the activity measurement is higher by at least 10 to 20%, in particular, at least 30 to 50%, than the activity measurement of the negative control. Furthermore, it is possible to verify the structure of the glycoprotein additionally, for example, by means of HPLC. These methods are well known to the person skilled in the art and they are for example described in publications by Staudacher et al., 1998, Anal. Biochem. 246, 96-101; and by Staudacher et al., 1991, Eur. J. Biochem. 199, 745-751. This is also mentioned in the present application on page 5, first paragraph.

Such a method is described in more detail in the specification, including example 6 on page 27 of the present application.

However, even without these examples for measuring the activity of a potential fucosyl transferase, the person skilled in the art who knows in what way the α1,3-fucosyl transferase acts (e.g., which molecules it adds to which proteins and in which positions), whereby this information is published as mentioned in the specification of the present application, will be able to set up and design a protocol with which the activity of a given transferase can be tested.

Therefore, in order to test whether a given DNA molecule falls under the scope of protection of the present application, one part of the method will be carried out electronically and therefore is certainly not an undue burden and the second part of the method comprises a biochemical activity test which can be carried out even in a high throughput assay which means that a large number of proteins can be tested at once.

With the data given in the present application sufficient information is provided to allow a person skilled in the art using his common general knowledge to perform the invention (to decide whether or not a given DNA molecule shows the features according to the claims of the present application) without undue burden and without needing inventive skills. Of course, theoretically a large number of potential candidates of DNA molecules show 50% homology to the sequence according to SEQ ID NO: 1. However, the activity assay does not constitute undue burden to the person skilled in the art. On the contrary, with the help of high throughput techniques which belong to basic laboratory methods the test with respect to α1,3-

fucosyl transferase activity can be carried out quickly and efficiently, e.g., without undue burden.

In conclusion, applicants submit that the present application provides sufficient written description support so as to reasonably convey to one skilled in the art that applicants had possession of the entire scope of the claimed invention. Thus, withdrawal of the written description requirement under 35 U.S.C. § 112, first paragraph, is respectfully requested.

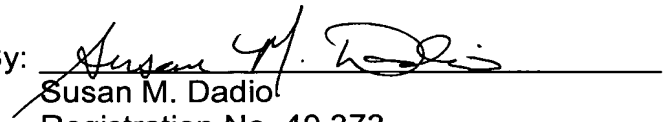
In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: September 30, 2004

By: 
Susan M. Dadio
Registration No. 40,373

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620